

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
31 March 2005 (31.03.2005)

PCT

(10) International Publication Number
WO 2005/029067 A3

(51) International Patent Classification⁷: **G01N 33/48**,
C12Q 1/68

TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM,
ZW.

(21) International Application Number:
PCT/JP2004/011741

(84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

(22) International Filing Date: 10 August 2004 (10.08.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/505,571 24 September 2003 (24.09.2003) US

Declarations under Rule 4.17:

- *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for the following designations* AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, *ARIPO patent* (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), *Eurasian patent* (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), *European patent* (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), *OAPI patent* (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)
- *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for all designations*

(71) Applicants (*for all designated States except US*): **ONCOTHERAPY SCIENCE, INC.** [JP/JP]; 3-16-13, Shirokanedai, Minato-ku, Tokyo, 1080071 (JP). **THE UNIVERSITY OF TOKYO** [JP/JP]; 3-1, Hongo 7-chome, Bunkyo-ku, Tokyo, 1138654 (JP).

(72) Inventors; and

(75) Inventors/Applicants (*for US only*): **NAKAMURA, Yusuke** [JP/JP]; 17-33, Azamino 1-chome, Aoba-ku, Yokohama-shi, Kanagawa, 2250011 (JP). **KATAGIRI, Toyomasa** [JP/JP]; 2-10-11-305, Higashigotanda, Shinagawa-ku, Tokyo, 1410022 (JP). **NAKATSURU, Shuichi** [JP/JP]; 6-2, Shimoochiai 2-chome, Chuo-ku, Saitama-shi, Saitama, 3380002 (JP).

(74) Agents: **SHIMIZU, Hatsushi et al.**; Kantetsu Tsukuba Bldg. 6F, 1-1-1, Oroshi-machi, Tsuchiura-shi, Ibaraki, 3000847 (JP).

Published:

- *with international search report*
- *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

(81) Designated States (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM,

(88) Date of publication of the international search report:
18 August 2005

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: METHOD OF DIAGNOSING BREAST CANCER

(57) Abstract: Compositions and objective methods for detecting, diagnosing, and treating breast cancer (BRC) are described herein. In particular, the present invention describes three BRC-associated genes, referred to herein as A5657, B9769, and C7965, up-regulated in BRC cells as compared to normal cells. In one embodiment, the diagnostic method involves determining the expression level of a BRC-associated gene that discriminates between BRC cells and normal cells; in an alternate embodiment, the diagnostic method involves determining the expression level of a BRC-associated gene that discriminates among BRC cells, between DCIS cells and IDC cells. The present invention further provides methods of screening for therapeutic agents useful in the treatment of breast cancer, methods of treating breast cancer and methods for vaccinating a subject against breast cancer.

WO 2005/029067 A3